THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, et al.,	:	
	:	
Plaintiffs,	:	
v.	:	C.A. No. 18-88-LPS
	:	
APOTEX INC., et al.,	:	
	:	
Defendants.	:	

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MEMORANDUM ORDER

June 26, 2020
(UNSEALED ON
JUNE 29, 2020)
Wilmington,
Delaware

STARK, U.S. District Judge:

Pending before the Court is Defendants Sandoz Inc. and Lek Pharmaceuticals d.d.'s (collectively, "Sandoz") motion to dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) and, alternatively, for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c). (D.I. 415)[1] The motion is fully briefed. (*See* D.I. 416, 426, 432, 648, 654) The court heard oral argument on December 18, 2019. (*See* D.I. 642) ("Tr.") For the reasons stated below, the Court will deny Sandoz's motion to dismiss for lack of subject matter jurisdiction but will grant Sandoz's motion for partial judgment on the pleadings. All claims and counterclaims against or by Sandoz which relate to the "polymorph patents" will be dismissed without prejudice.

BACKGROUND

Plaintiffs H. Lundbeck A/S, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc. ("Plaintiffs") brought this patent infringement case against Sandoz based on Sandoz's Abbreviated New Drug Applications ("ANDA"), which seek approval from the U.S. Food and Drug Administration ("FDA") to market generic versions of Plaintiffs' Trintellix drug product ("Sandoz's ANDA product") prior to the expiration of certain of Plaintiffs' patents.

[1] *See generally* D.I. 416 at 15 n.12 (Sandoz: "The Federal Circuit has not yet decided whether a dismissal based on an ANDA filer's conversion from Paragraph IV to Paragraph III certifications should be for failure to state a claim under Fed. R. Civ. P. 12(b)(6)/12(c) or lack of jurisdiction under Fed. R. Civ. P. 12(b)(1)."); D.I. 432 at 1 (Sandoz: "Dismissal of Counts I-IV is required under Fed. R. Civ. P. 12(c) and/or 12(b)(1).").

In connection with its ANDA, Sandoz filed Paragraph IV certifications[2] for Plaintiffs' four crystal polymorph patents: U.S. Patent Nos. 8,722,684 ("'684 patent"), 8,969,355 ("'355 patent"), 9,227,946 ("'946 patent"), and 9,861,630 ("'630 patent") (collectively, the "polymorph patents"). (D.I. 416 at 1) Sandoz also filed Paragraph III certifications[3] for two of Plaintiffs' patents related to the active compound vortioxetine: U.S. Patent Nos. 7,144,884 ("'884 patent") and 8,476,279 ("'279 patent") (the "compound patents"). (D.I. 416 at 1)

After receiving Sandoz's certifications, Plaintiffs filed suit. Counts I through IV of the Second Amended Complaint ("Complaint") allege that the filing of Sandoz's ANDA seeking final FDA approval prior to the expiration of the four polymorph patents is an act of infringement pursuant to 35 U.S.C. § 271(e)(2). (D.I. 275 at ¶¶ 65, 77, 89, 101) Sandoz filed an answer and counterclaims, which included counterclaims I through IV, seeking a declaratory judgment of non-infringement of each of the polymorph patents. (*See* D.I. 323)

On May 29, 2019, the Court allowed Plaintiffs to amend their Complaint to add counts for infringement of two additional "Orange Book"[4] listed patents – U.S. Patent Nos. 9,125,910

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[2] A Paragraph IV certification is an ANDA filer's statement that it intends to market its bioequivalent pharmaceutical product before the expiration of a patent listed as covering that product because the ANDA filer believes such patent is either not infringed or is invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338-39 (Fed. Cir. 2003).

[3] A Paragraph III certification is an ANDA filer's statement it will not market its bioequivalent pharmaceutical product until after expiration of a patent listed as covering that product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1374 (Fed. Cir. 2012).

[4] The "Orange Book" is an FDA publication in which holders of New Drug Applications list all patents that may cover their products. *See* 21 U.S.C. § 355(b)(1); *Dey Pharma, LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158, 1159 (Fed. Cir. 2012).

("'910 patent") and 9,278,096 ("'096 patent") – which Sandoz refers to as "non-MDD patents."[5] (D.I. 260) Shortly thereafter, on June 26, 2019, Sandoz converted its Paragraph IV certifications for the polymorph patents to Paragraph III certifications. (D.I. 416 at 7) "[A]s a result [Sandoz] is not seeking ANDA approval before the date on which the last of those patents expires – more than 10 years from now, i.e., June 30, 2031." (*Id.* at 1)

Sandoz notified Plaintiffs of its change from Paragraph IV to Paragraph III certifications and asked Plaintiffs to agree to a stipulated dismissal of Sandoz from this action. (D.I. 417 Ex. I at 46) In response, Plaintiffs asked Sandoz to "stipulate that they will not convert their Paragraph III certifications for [the polymorph patents] back to Paragraph IV certifications at a future date," adding that "we do not believe it would be appropriate to dismiss the case if Sandoz/Lek reserve[s] the right to convert their certifications back to Paragraph IV and resurrect the litigation at a later date." (D.I. 417 Ex. I at 43) Two weeks later, Sandoz refused to "agree not to re-convert to PIV [i.e., Paragraph IV] at a future date," suggesting it would be unreasonable to make and disclose business plans more than ten years in advance. (D.I. 417 Ex. I at 43) Instead, Sandoz offered to stipulate that "it will be bound by a final judgment with respect to validity and infringement for the other defendants." (D.I. 417 Ex. I at 43) Plaintiffs declined Sandoz's offer. (D.I. 416 at 7) Sandoz then filed its pending motion. (D.I. 415)

[5] Sandoz characterizes what it calls the "non-MDD patents" as being directed to methods of treatment for indications other than major depressive disorder. (*See* D.I. 416 at 6) Counts V through VIII of the Complaint allege infringement of the non-MDD patents by Sandoz (D.I. 260 at ¶¶ 108-59), and Sandoz's Counterclaims IX through XII seek declaratory judgments of non-infringement and invalidity of these same non-MDD patents (D.I. 323 at ¶¶ 93-124). The Court agrees with Sandoz that the Court's decision to allow Plaintiffs to add claims for infringement of these patents does not control the outcome of the instant motion. (*See* D.I. 432 at 2) The parties will be provided an opportunity to update the Court on the status of their disputes with respect to the non-MDD patents and how the Court should proceed with respect to them.

LEGAL STANDARDS

A. Motion to Dismiss for Lack of Subject Matter Jurisdiction

Federal Rule of Civil Procedure 12(b)(1) "authorizes dismissal of a complaint for lack of jurisdiction over the subject matter, or if the plaintiff lacks standing to bring his claim." *Samsung Elecs. Co., Ltd. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645, 648 (D. Del. 2008). "At issue in a Rule 12(b)(1) motion is the court's very power to hear the case." *Petruska v. Gannon Univ.*, 462 F.3d 294, 302 (3d Cir. 2006) (internal quotation marks omitted). Usually, a motion to dismiss for lack of subject matter jurisdiction presents either a facial or factual challenge. *See CNA v. United States*, 535 F.3d 132, 139 (3d Cir. 2008). A facial attack "concerns an alleged pleading deficiency," while a factual attack concerns the "failure of a plaintiff's claim to comport factually with the jurisdictional prerequisites." *Id.* (internal quotation marks and brackets omitted). With respect to factual attacks,

> there is substantial authority that the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case. In short, no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. Moreover, the plaintiff will have the burden of proof that jurisdiction does in fact exist.

Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977).

Defendants' 12(b)(1) motion presents a factual attack. (*See* D.I. 416 at 2) ("The sole trigger for suit – Sandoz Inc.'s original Paragraph IV certifications – no longer exists, leaving the Court without the jurisdictional hook established by the Hatch-Waxman Act.")

B. Motion for Judgment on the Pleadings

Pursuant to Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "[a]fter pleadings are closed – but early enough not to delay trial." When evaluating a defendant's motion for judgment on the pleadings, the Court must accept all factual allegations in a complaint as true and view them in the light most favorable to the non-moving party. *See Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008); *see also Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000). This is the same standard that applies to a Rule 12(b)(6) motion to dismiss. *See Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). A Rule 12(c) motion will not be granted "unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Rosenau*, 539 F.3d at 221.

"The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference." *Venetec Int'l, Inc. v. Nexus Med., LLC*, 541 F. Supp. 2d 612, 617 (D. Del. 2008); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (explaining that any documents integral to pleadings may be considered in connection with Rule 12(c) motion). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Burlington Coat Factory*, 114 F.3d at 1420. Thus, a court may grant a motion for judgment on the pleadings (just as with a motion to dismiss) only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio*, 221 F.3d at 482 (3d Cir. 2000).

The Court may consider matters of public record as well as authentic documents upon which the complaint is based if attached to the complaint or as an exhibit to the motion. *See Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 n.2 (3d Cir. 1994). The Court may also take judicial notice of the factual record of a prior proceeding. *See Oneida Motor Freight, Inc. v. United Jersey Bank*, 848 F.2d 414, 416 n.3 (3d Cir. 1988). Ultimately, a motion for judgment on the pleadings can be granted "only if no relief could be afforded under any set of facts that could be proved." *Turbe*, 938 F.2d at 428.

DISCUSSION

A. Sandoz's Motion to Dismiss for Lack of Subject Matter Jurisdiction

Sandoz argues that it "eliminated the jurisdictional hook" for Plaintiffs' infringement claims relating to the polymorph patents by converting its Paragraph IV certifications for these patents to Paragraph III certifications. (D.I. 416 at 15) The Court disagrees.

"[T]he requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2)." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012); *see also Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1124 (Fed. Cir. 2018) (holding that subject matter jurisdiction exists when plaintiff alleges that ANDA filer infringed plaintiff's patent "by filing the ANDA"). Thus, when a defendant in an ANDA lawsuit converts a Paragraph IV certification to a Paragraph III certification during the course of a lawsuit, the Court is "not deprived of jurisdiction under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 1338(a) because it is sufficient that the case was initially certified under Paragraph IV." *Sanofi v. Lupin Atlantis Holdings Sa*, 2017 WL 384062, at *1 (D. Del. Jan. 26, 2017); *see also Astrazeneca AB v. Aurobindo Pharma Ltd.*, 2016

2016 U.S. Dist. LEXIS 195936, at *4 n.3 (D. Del. Sept. 15, 2016). Further, these conversions do not moot the case unless defendants meet "the formidable burden of showing that it is absolutely clear the alleged wrongful behavior could not reasonably be expected to recur." *Sanofi*, 2017 WL 384062, at *2; *see also Ferring B.V. v. Watson Labs, Inc.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014) ("A case becomes moot when interim relief or events have eradicated the effects of a defendant's act or omission, and there is no reasonable expectation that the alleged violation will recur."); *Astrazeneca AB*, 2016 U.S. Dist. LEXIS 195936, at *4 n.3.

In this action, the Court obtained subject matter jurisdiction once Plaintiffs alleged that Sandoz's ANDA filing infringed the polymorph patents. Because "the case was initially certified under Paragraph IV," the Court's jurisdiction did not disappear when Sandoz converted its Paragraph IV certifications to Paragraph III certifications. *See Sanofi*, 2017 WL 384062, at *1. Further, Sandoz has not met its "formidable burden" to show that it will not repeat its wrongful conduct. Instead, Sandoz has expressly refused to stipulate that it will not reconvert to a Paragraph IV certification (D.I. 417 Ex. I at 43), adding that it "simply cannot state with any certainty what its business strategy will be nearly seven years from now" (D.I. 416 at 14). Thus, while reconversion may only be "hypothetical" at this point (D.I 416 at 18), Sandoz has not shown that it is "absolutely clear the alleged wrongful behavior could not reasonably be expected to recur."

Accordingly, the Court will deny Sandoz's motion to dismiss for lack of subject matter jurisdiction.

B. Sandoz's Motion for Judgment on the Pleadings

As an alternative to dismissal for lack of subject matter jurisdiction, Sandoz moves for judgment on the pleadings with respect to the polymorph patents, on the ground that Plaintiffs have failed to state a claim on which relief may be granted. (*See* D.I. 416 at 9-15) The Court is persuaded it should grant this portion of Sandoz's motion.

Plaintiffs originally sought relief under 35 U.S.C. § 271(e)(2), which deems it "an act of infringement" to submit an ANDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent ***before the expiration of such patent***" (emphasis added). (*See also* D.I. 275 at ¶¶ 61-107) Plaintiffs specifically alleged in the Complaint that their basis for these claims was Sandoz's "submitting [their] ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® ***prior to the expiration*** of the [polymorph] patent[s]." (D.I. 275 at ¶¶ 65, 77, 89, 101) (emphasis added) However, when Sandoz converted to Paragraph III certifications, Sandoz created circumstances under which "the FDA will only approve [its] ANDA ***after*** the [polymorph] patent[s] ha[ve] expired." *Amerigen Pharm. Ltd. v. UCB Pharma GmBH*, 913 F.3d 1076, 1083 (Fed. Cir. 2019) (emphasis added). It is now clear from the pleadings that Sandoz no longer seeks FDA approval of its ANDA product "before the expiration of the [polymorph] patent[s]." Indeed, Plaintiffs concede that they "don't have a live dispute on whether [Sandoz] want[s] to market [its ANDA product] before [Plaintiffs'] patent[s] expire[]" – which had been the very basis for their § 271(e)(2) claims. (*See* Tr. at 80) Therefore, it is presently clear that Plaintiffs cannot obtain relief on their claim for infringement under § 271(e)(2). Accordingly, Counts I through IV of the Complaint should be

dismissed for failure to state a claim on which relief may be granted, and Sandoz has shown it is entitled to judgment on the pleadings.[6]

This conclusion is confirmed by looking to the statutory provision setting out the relief Plaintiffs seek in their Complaint: § 271(e)(4). "[T]he remedy for a prevailing plaintiff [on a claim for infringement brought under § 271(e)(2)] is an injunction delaying approval of a defendant's ANDA until expiration of all listed Orange Book patents." *Astrazeneca AB*, 2014 U.S. Dist. LEXIS 79201, at *16. Here, pursuant to § 271(e)(4), Plaintiffs seek an order from the Court prohibiting the FDA from giving final approval to Sandoz's ANDA until after the expiration of the polymorph patents. (*See* D.I. 275 at 30) Sandoz, by converting from Paragraph IV to Paragraph III, has already essentially given Plaintiffs what they asked for from the Court. By Sandoz's own actions, the FDA cannot now give final approval to Sandoz's ANDA until after the expiration of the polymorph patents. There is no additional relief the Court can now provide.

Plaintiffs have offered several reasons why their claims should survive dismissal. None is persuasive.

[6] Although Sandoz's motion is brought pursuant to Rule 12(c), it is clear that Sandoz is not seeking a judgment of non-infringement (i.e., a merits ruling that its ANDA product does not infringe Plaintiffs' patents). Instead, Sandoz seeks dismissal of Counts I-IV of the Complaint for failure to state a claim upon which relief may be granted. (*See, e.g.*, D.I. 416 at 9 ("**Counts I-IV of Takeda's Second Amended Complaint Should Be Dismissed for Failure to State a Claim Upon Which Relief Can Be Granted under Fed. R. Civ. P. 12(c)**"); *see also* Tr. at 70-71 (Sandoz counsel explaining same)) The "judgment" the Court is granting is dismissal of Plaintiffs' polymorph patent infringement claims (as well as Sandoz's counterclaims for non-infringement) without prejudice, just as Sandoz has requested. (*See, e.g.*, D.I. 416 at 10) ("Counts I-IV of Takeda's Second Amended Complaint and Sandoz's Counterclaims I-VIII should be dismissed without prejudice.")

First, when asked at oral argument to identify the claim upon which they could obtain relief, Plaintiffs said that "the basis that you could do it is that [Sandoz] started out as a Paragraph IV." (Tr. at 79) However, Sandoz no longer seeks approval under Paragraph IV, so any argument about Sandoz's initial certification speaks only to the Court's subject matter jurisdiction – not to whether Plaintiffs any longer have a claim to relief under § 271(e)(2).

Second, Plaintiffs argued at the hearing that "the product that is the subject of [Sandoz's] ANDA infringes our patents, so we have a live infringement claim." (Tr. at 80) However, the inquiry under 35 U.S.C. § 271(e)(2) is not simply whether the product described in the ANDA infringes Plaintiffs' patent, but "whether ***what the generic drug maker is requesting authorization for in the ANDA*** would be an act of infringement if performed." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (emphasis added). Sandoz seeks authorization to market its ANDA product only ***after*** the polymorph patents expire. At that point, Sandoz will not be committing "an act of infringement" under § 271(e)(2).

Plaintiffs argue that Sandoz's conversion to Paragraph III certifications "does not conclusively establish that Sandoz does not intend to market its generic product prior to the expiration of the [polymorph patents]," especially given that Sandoz refuses to stipulate that it will not reconvert to Paragraph IV. (D.I. 426 at 18-19) But § 271(e)(2) "does not encompass speculative claims of infringement." *Warner-Lambert*, 316 F.3d at 1364 (internal quotation marks omitted). Hence, Plaintiffs' suggestion that Sandoz ***might*** reconvert to Paragraph IV and, therefore ***might*** infringe during the term of the polymorph patents, does not give rise to a claim under § 271(e)(2). Rather, "the ANDA must be judged ***on its face*** for what an accused infringer seeks the FDA's approval to do." *Warner-Lambert*, 316 F.3d at 1364 (emphasis added). On its

face, Sandoz's ANDA now seeks FDA approval for Sandoz's ANDA product only ***after*** the polymorph patents expire. Thus, Plaintiffs cannot obtain relief and Sandoz is entitled to dismissal.

Finally, Plaintiffs suggest that relief the Court could still provide (upon a post-trial finding that Sandoz's ANDA product infringes a valid claim of a polymorph patent) is an injunction against Sandoz to prevent it from reconverting from Paragraph III to Paragraph IV. (*See* Tr. at 80-81) In the Court's view, such relief would be inappropriate – given the utterly speculative nature of the claim on which it would be based,[7] as Sandoz has no present intent to seek FDA approval prior to the expiration of the polymorph patents – and, accordingly, is not truly available. "A claim is not ripe for adjudication if it rests on contingent future events that may not occur as anticipated, or indeed may not occur at all." *AstraZeneca*, 669 F.3d at 1380-81 (internal quotation marks omitted). As Plaintiffs' claim is not ripe for adjudication, it follows that there is no relief the Court may properly grant.

In sum, because "no relief could be afforded under any set of facts that could be proved," Sandoz's motion will be granted. *Turbe*, 938 F.2d at 428. Plaintiffs' claims, and Sandoz's

[7] It is worth noting that, as Sandoz itself explains, reconversion to Paragraph IV would leave Sandoz "disadvantaged relative to its competitors," many of whom remain parties to the instant lawsuit, because "(i) the Paragraph III certification would already have impacted the priority of the FDA's review of the [Sandoz] ANDA; and (ii) conversion to Paragraph IV would trigger a new 30-month stay" of FDA approval. (D.I. 416 at 4 n.3; *see also* D.I. 432 at 7-8 ("By converting to Paragraph III, Sandoz Inc. cannot simply pick up where it left off because it has irrevocably forfeited its first-to-file status, given up its spot in the FDA's queue for approval, and will be subjected to a new 30-month stay should it reconvert . . .").)

counterclaims, relating to infringement of the polymorph patents will be dismissed without prejudice[8] for failure to state a claim on which relief may be granted.

CONCLUSION

For the foregoing reasons, Sandoz's motion to dismiss for lack of subject matter jurisdiction is denied and Sandoz's motion for partial judgment on the pleadings is granted. An appropriate order follows.

[8] At the hearing, Plaintiffs belatedly asked that dismissal of Sandoz's counterclaims be ***with prejudice***, even while dismissal of Plaintiffs' claims would be ***without prejudice***. (*See* Tr. at 90-91) Plaintiffs' request comes too late. *See, e.g., Watkins v. Int'l Union, Sec., Pol. and Fire Prof'ls of Am.*, 2016 WL 1166323, at *4 n.4 (D. Del. Mar. 23, 2016) ("Because this argument was made for the first time at the hearing, the Court will not consider it."); *see also Tomasko v. Ira H. Weinstock, P.C.*, 357 Fed. App'x 472, 479 (3d Cir. Dec. 18, 2009) ("[W]e find that the specific objections . . . raised for the first time at oral argument in the District Court have been waived."). Additionally, Plaintiffs' request is not meritorious. (*See* D.I. 648 at 1) ("Dismissing Plaintiffs' claims ***without*** prejudice while dismissing Sandoz Inc.'s claims ***with*** prejudice would place the parties on a different legal footing and thereby unfairly prejudice Sandoz Inc.")